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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/665,867	09/19/2003	Ann Marie Schmidt	55873-BA-PCT-US/JPW/AJM/A	6756

7590

03/28/2006

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New York, NY 10036

EXAMINER

EMCH, GREGORY S

ART UNIT	PAPER NUMBER
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1649

DATE MAILED: 03/28/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b> 10/665,867	<b>Applicant(s)</b> SCHMIDT ET AL.	
	<b>Examiner</b> Gregory S. Emch	<b>Art Unit</b> 1649	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 10 January 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

## **DETAILED ACTION**

### ***Formal Matters***

Claims 4, 18, 19 and 23 were canceled in the communication dated 20 January 2006. Claim 17 is pending and under consideration.

### ***Claim Rejections Withdrawn***

The statutory and nonstatutory double patenting rejections of claim 17 are rendered moot by cancellation of claim 17 in co-pending Application No. 10/990,310 and by cancellation of claims 53-57 in co-pending Application No. 10/783,635 and are thus withdrawn.

New and remaining issues are set forth below.

The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

### ***Claim Rejections - 35 USC § 101***

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 17 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, the claim is directed to "an antibody." In the instant case, "an antibody" can refer to one that is still in a living being.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 17 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Applicants are directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. §112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

The claim is directed to an antibody immunoreactive with an epitope comprising a unique sequence of EN-RAGE.

This is a genus claim. The specification and claim do not set forth the structure of the multitude of potential epitopes encompassed by the claim. Thus, the scope of the claim includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although the specification states that these types of changes are routinely done in the

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art, the specification and claim do not provide guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the amino acid class are missing from the disclosure. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, an epitope comprising a unique sequence of EN-RAGE is insufficient to describe the genus. One of skill in the art would reasonably conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicants were not in possession of the claimed genus.

***Claim Rejections - 35 USC § 112 second paragraph***

The rejection of claim 17 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite is maintained for reason of record in the office action dated 14 October 2005 and as set forth *infra*.

In the Response filed 20 January 2006, Applicants assert that the term "unique," in the context of claim 17, would be clearly understood by one of skill in the art to mean that the claimed antibody is immunoreactive with an epitope comprising an amino acid sequence of EN-RAGE, wherein that amino acid sequence is unique to EN-RAGE. That is, the amino acid sequence "unique" to EN-RAGE is found within EN-RAGE but not in other proteins.

Applicants' argument has been fully considered and is not found persuasive. While the Examiner agrees that the Applicants' explanation of a "unique sequence of EN-RAGE" is reasonable to conclude, it is submitted that of skill in the art may not have the same interpretation. For example, the phrase may read on a sequence of EN-RAGE, e.g., a variant, that is discovered in the future, which would be "unique" because it had not been previously isolated or generated. The term "unique" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

***Claim Rejections - 35 USC § 102***

The rejection of claim 17 under 35 U.S.C. 102(b) as being anticipated by EP07311166A2 to Hitomi et al is maintained for reason of record in the office action dated 14 October 2005 and as set forth *infra*.

The claim is directed to an antibody immunoreactive with an epitope comprising a unique sequence of EN-RAGE.

In the Response filed 20 January 2006, Applicants assert that the teaching of Hitomi et al., i.e., an antibody to a polypeptide that is not identical to EN-RAGE, does not constitute a teaching of applicants' antibody.

Applicants' argument has been fully considered and is not found persuasive.

As stated previously, the '166 document teaches antibodies to peptides that comprise sequences that are 92% identical to Applicants' SEQ ID NO: 2. Cross-

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reactivity of antibodies is a common occurrence, especially in antibodies that bind to similar proteins. U.S. Patent No. 6,787,637 to Schenk discloses that when an antibody is said to bind to an epitope within specified residues, the antibody specifically binds to a polypeptide containing the specified residues. Such an antibody does not necessarily contact every single amino acid residue within the epitope; nor does every amino acid substitution or deletion within the epitope necessarily affect binding (col. 14, lines 1-8). The peptide of Hitomi et al. contains scattered mismatched residues (at residues 14, 30, 36 and 47) when compared to Applicants' SEQ ID NO: 2. Therefore, in the instant case since single amino acid substitutions do not necessarily affect epitope binding, it is reasonable to conclude that an antibody that binds to an amino acid sequence that is 92% identical to EN-RAGE would also bind an antibody that binds to an epitope comprising a unique sequence of EN-RAGE. Since the patent discloses all the elements of the claim, claim 17 is anticipated by EP07311166A2 to Hitomi et al.

### ***Conclusion***

No claim is allowed.

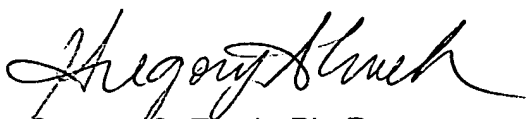
  
JANET D. ANDRES  
SUPERVISORY PATENT EXAMINER

***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gregory S. Emch whose telephone number is (571) 272-8149. The examiner can normally be reached on Monday through Friday from 9AM to 5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Janet L. Andres can be reached at (571) 272-0867. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gregory S. Emch, Ph. D.  
Patent Examiner  
Art Unit 1649  
March 21, 2006



JANET L. ANDRES  
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